REMARKS

Claims 1-5 and 7 have been amended. Claim 6 has been canceled. Claim 11 has been added. Claims 1-5 and 7-11 are now pending. Claims 8-10 are withdrawn relating to a non-elected invention. Applicants reserve the right to pursue the original claims in this and other applications. The Title of the Invention has been amended to correspond more closely to the pending claims. Applicants respectfully request reconsideration of the above-referenced application in light of the amendments and following remarks.

Claims 1, 3 and 5 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The rejection is respectfully traversed.

The Office Action asserts that it is unclear: a) how 'acid moieties' alone can derivatize polypeptides; b) what is coupled to the polypeptide; and c) whether the derivatized polypeptide or the polypeptide coupled with something has a pKa of less than 2. Applicants respectfully submit that these terms are clear and definite when viewed in light of Applicants' specification.

"[T]he definiteness of the language employed must be analyzed - not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235 (CCPA 1971) (emphasis added). As such, a claim may appear indefinite when read in a vacuum, but may be definite upon reviewing the application disclosure or prior art teachings. This is a situation that arises in the present case.

For example, Applicants' specification provides that "the acidity of the derivatizing group(s) [i.e.,] (acidic moiety) has a profound effect on the resulting mass spectra." (p. 7, ll. 17-18). In other words, Applicants' specification defines an 'acidic moiety' or 'acidic moieties' is the derivatizing group itself. The claimed term 'when coupled' means "that the pKas of the acidic moieties is defined as measured after [the derivatizing group(s) is] covalently bonded with a polypeptide or a peptide." (Applicants' specification, p. 7, ll.33-35) (emphasis added). Thus, the derivatizing group is covalently bonded or coupled to the polypeptide and its pKa is less than 2. Claim 1 is definite upon reviewing Applicants' specification. Consequently, the § 112, second paragraph, rejection of claim 1 should be withdrawn.

Next, the Office Action asserts that the limitation, "pKas of less than 2," recited in claim 1, is meaningless without information related to pH. Again, the Examiner's attention is respectfully directed to Applicants' specification p. 7, ll. 15-35. One feature of the present invention is "derivatization of a polypeptide . . . with one or more of a relatively strong acids, i.e., acidic moieties having pKas less than about 2, preferably less than about 0, and more preferably less than about -2, when coupled with a polypeptide or peptides of the polypeptide." (Applicants' specification, p. 7, ll. 27-30) (emphasis added). Claim 1 is definite upon reviewing Applicants' specification. The pKa is acidic in relation to the pH. Consequently, the § 112, second paragraph, rejection of claim 1 should be withdrawn.

Next, the Office Action asserts that the limitation, "commercially available software," recited in claim 3 is not proper. Claim 3 has been amended to omit the offending claim language. Specifically, claim 3 recites, inter alia, "comparing the fragmentation pattern against a database." Consequently, the § 112, second paragraph, rejection of claim 3 should be withdrawn.

Finally, the Office Action asserts that the limitation, "a method . . . characterized in the peptides . . . are produced by digestion," recited in claim 5, is unclear if it is an actual method step or intended to be a further limitation of the peptides of claim 1. Claim 5 has been amended to clarify that it is a further limitation of the peptides in that they are enzymatically or chemically formed (Applicants' specification, p. 8, ll. 6-28). Specifically, claim 5 recites, inter alia, that "at least one peptide of the polypeptide is produced by enzymatic or chemical digestion." Consequently, the § 112, second paragraph, rejection of claim 5 should be withdrawn.

Claims 1, 4 and 5 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the article: Rapid Communication is Mass Spectrometry ("Knierman"). The rejection is respectfully traversed.

In an anticipation rejection, "[n]o question of obviousness is present. In other words, for anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present." M.P.E.P. § 706.02 (emphasis added). Applicants respectfully submit that the Office Action has not set forth a proper case of anticipation under 35 U.S.C. §

102(b). Knierman does not disclose or teach, explicitly or inherently, every aspect of Applicants' claimed invention that is recited in claims 1, 4 and 5.

For example, Knierman does not disclose a method of derivatizing with at least one acidic moiety having a pKa of less than about 2 when coupled with a polypeptide or at least one peptide of the polypeptide. As indicated above, Applicants' claimed derivatizing group (acidic moiety) is covalently bonded or coupled to a polypeptide or the peptides of the polypeptide and its pKa is less than 2. Knierman merely teaches digestion of peptides using trifluoroacetic acid and HCl. This is not the same as the step of providing "at least one acidic moiety having a pKa of less than about 2, when coupled with a polypeptide or at least one peptide of the polypeptide," as recited in claim 1.

As such, the cited reference does not teach a method of sequencing a polypeptide comprising, "derivatizing a N-terminus of a polypeptide or an N-termini of at least one peptide of the polypeptide with at least one acidic moiety having a pKa of less than about 2, when coupled with a polypeptide or at least one peptide of the polypeptide, to provide at least one derivatized analyte; (b) analyzing the at least one derivatized analyte using a mass spectrometric technique to provide a fragmentation pattern; and (c) interpreting the fragmentation pattern."

Claims 4 and 5 depend from claim 1 and should be similarly allowable with claim 1 for at least the reasons provided above, and on their own merits. Consequently, the § 102(b) rejection of claims 1, 4 and 5 should be withdrawn.

Claims 1-7 stand rejected under 35 U.S.C. § 102(a) and § 102(e) as being anticipated by U.S. Patent No. 6,558,902 ("Hillenkamp"). The rejection is respectfully traversed.

Hillenkamp does not disclose a method of derivatizing with at least one acidic moiety having a pKa of less than about 2 when coupled with a polypeptide or at least one peptide of the polypeptide. Hillenkamp merely teaches cleaving terminal amino acids with Edman's reagent, i.e., an acid. This is not the same as the step of providing "at least one acidic moiety having a pKa of less than about 2, when coupled with a polypeptide or at least one peptide of the polypeptide," as recited in claim 1 (emphasis added).

Claims 2-7 depend from claim 1 and should be similarly allowable with claim 1 for at least the reasons provided above, and on their own merits. Consequently, the § 102(a) and 102(e) rejection of claims 1-7 should be withdrawn.

Claims 1, 2, and 4-6 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Knierman in view of the article: Mass Spectrometry Reviews ("Roth"). The rejection is respectfully traversed.

For similar reasons provided above, Knierman does not teach or suggest a method of derivatizing with at least one acidic moiety having a pKa of less than about 2 when coupled with a polypeptide or at least one peptide of the polypeptide. Knierman merely discloses the digestion of peptides using trifluoroacetic acid and HCl. This is not the same as the step of providing "at least one acidic moiety having a pKa of less than about 2, when coupled with a polypeptide or at least one peptide of the polypeptide," as recited in claim 1 (emphasis added). Applicants' claimed derivatizing group (acidic moiety) is covalently bonded or coupled to a polypeptide or the peptides of the polypeptide and its pKa is less than 2.

Roth is relied upon for disclosing the use of MALDI-PSD mass spectrometry for peptide analysis, and adds nothing to rectify the deficiencies associated Knierman. Claims 2 and 4-6 depend from claim 1 and should be similarly allowable with claim 1 for at least the reasons provided above, and on their own merits. Consequently, the § 103(a) rejection of claims 1, 2 and 4-6 should be withdrawn.

Claims 1-3, 5 and 6 stands provisionally rejected under the judicially-created doctrine of obviousness-type double-patenting as being unpatentable over claims 1-3, 5, and 10 of co-pending Application No. 09/863,786. The provisional rejection is respectfully traversed.

As indicated above, claim 1 has been amended and as such, is not obvious over claims 1-3, 5, and 10 of co-pending application no. 09/863,786. Claim 1 now recites a method of sequencing a polypeptide comprising, "derivatizing a N-terminus of a polypeptide or an N-termini of at least one peptide of the polypeptide with at least one acidic moiety having a pKa of less than about 2, when coupled with a polypeptide or at least one peptide of the polypeptide, to provide at least one derivatized analyte; (b) analyzing the at least one derivatized analyte using a mass spectrometric technique to

provide a fragmentation pattern; and (c) interpreting the fragmentation pattern." As acknowledged by the Office Action, the "conflicting claims are not identical," (p. 8) and with the present amendments, are not obvious variants of each other. As such, the provisional obviousness-type double-patenting rejection should be withdrawn.

Moreover, Applicants respectfully submit that the prior art of record does not disclose or suggest the subject matter of newly added claim 11. For instance, the prior art does not teach or suggest a method of sequencing a polypeptide comprising, "adding at least one acidic group to the N-terminus of a polypeptide or at least one peptide formed through cleavage of the polypeptide; coupling the at least one acidic group to the N-terminus, wherein said coupled polypeptide or at least one peptide has a pKa of less than about 2; providing at least one derivatized analyte with a mass spectra predominantly characterized by y-ions; and analyzing the at least one derivatized analyte," as recited in claim 11. The prior art simply does not disclose or suggest coupling an acidic group to the N-terminus, wherein said coupled polypeptide or at least one peptide has a pKa of less than about 2, much less providing a derivatized analyte with a mass spectra predominantly characterized by y-ions. For at least these reasons, claim 11 is believed to be in immediate condition for allowance.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to review and pass this application to issue.

Respectfully submitted,
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